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10/684,777	10/14/2003	Darlene Coleman Deecher	WYNC-0716 (AM101156-1)	3353

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,777	DEECHER ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,13 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,13 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed January 26, 2007 have been received and entered into the application.

Action Summary

The claims 1-7 and 13-21 are rejected under 35 U.S.C. 112, first paragraph (enablement) is being maintained for the reasons stated in the previous Office Action and the rejection is modified in this Office Action to exclude cancelled claim 14.

The claims 1-7 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briley (WO 98/36744) in view of Leonard et al. (US 2003/0216366A1) is being maintained for the reasons stated in the previous Office Action and the rejection is modified in this Office Action to exclude cancelled claim 14.

Upon further consideration, following additional rejection have been made.

Therefore, this Office Action is made non-final.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7 and 13-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment vasomotor symptoms caused by thermoregulatory dysfunction comprising administering a structurally different compounds including desipramine or fluoxetine or combination of desipramine & fluoxetine, venlafaxine with their **"therapeutic effective amounts"**, but does not reasonably provide enablement for the "method for treating vasomotor symptoms caused by thermoregulatory dysfunction comprising administering **milnacipran in a therapeutically effective amount wherein the amount is less than about 37.5mg**". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating vasomotor symptoms caused by thermoregulatory dysfunction in a subject in need thereof, comprising the step of: administering to said subject a therapeutically effective amount of milnacipran or pharmaceutically acceptable

salt thereof, wherein said amount is less than about 37.5mg/day. The nature of the invention is complex in that it encompasses the actual treatment of vasomotor symptoms caused by thermoregulatory dysfunction (i.e. hot flushes) such that the subject treated with above compounds result in alleviation of vasomotor symptoms such as hot flushes.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass treatment of a vasomotor symptoms caused by thermoregulatory dysfunction in a subject comprising administering a compound that actually causes vasomotor symptoms.

Guidance of the Specification: The guidance given by the specification as to how the claimed compounds to a subject in its therapeutic amount (less than about 37.5mg/day) would actually treat vasomotor symptoms is minimal. All of the guidance provided by the specification is directed towards employment of a therapeutic amount of other NRI compound or SRI compound and other NRI/SRI compound wherein the amounts **are greater than** 37.5mg/day.

Working Examples: All of the working examples (e.g. Example 3) provided by the specification are directed toward the employment of the therapeutic amount **greater than** 37.5mg/day with other NRI compound or SRI compound and other NRI/SRI compound.

State of the Art: While the state of the art is relatively high with regard to administration of milnacipran in its therapeutic amount causes hot flushes, the state of the art with regard the **treatment of such disorders** by employment of a

therapeutic dose **less than about 37.5mg/day** is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compound was administered to a subject to treat vasomotor symptoms caused by thermoregulatory dysfunction such as hot flushes. The State of the Art, Spencer et al. (page 421) teaches opposite of Applicants' claimed invention that milnacipran actually causes hot flushes as an adverse event; and the incidence of hot flushed cause by milnacipran is higher than Tricyclics or SSRIs.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual employment of a therapeutic amount less than 37.5mg/day in a human subject for treatment of vasomotor symptoms caused by thermoregulatory dysfunction such as hot flushes with the claimed compound (milnacipran) makes practicing the claimed invention unpredictable in terms of actual treatment of vasomotor symptoms caused by thermoregulatory dysfunction with the amount set forth in the claims.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to undergo experimentation to test the milnacipran such as those claimed to determine whether or not any of dosages less than 37.5mg/day would actually capable of treating vasomotor symptoms, as instant specification does not show the treatment of hot flushes by administration of dosages less than 37.5mg/day of claimed compound. If unsuccessful, which is likely given the lack of significant guidance from the

specification or prior art regard to milnacipran causes vasomotor symptoms resulted from thermoregulatory dysfunction with its therapeutic amount, one of skill in the art would have to then either envision a modification of the claimed amount and the subjects medical profile including concomitant therapeutic compounds and their side effects, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding treatment of vasomotor symptoms with any compound with the claimed amount, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treat vasomotor symptoms caused by thermoregulatory dysfunction in a subject in need thereof, comprising the step of: administering to said subject a therapeutically effective amount of milnacipran or pharmaceutically acceptable salt thereof, wherein said amount is less than about 37.5mg/day.

Therefore, a method for treating vasomotor symptoms caused by thermoregulatory dysfunction in a subject in need thereof, comprising the step of: administering to said subject a therapeutically effective amount of milnacipran or pharmaceutically acceptable salt thereof, wherein said amount is less than about 37.5mg/day is not considered to be enabled by the instant specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 13 and 15-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 9, 10 and 13-19 of copending Application No. 10/685,974 in view of Berendensen (2000).

The claims in instant Application is drawn to a method for treating vasomotor symptoms caused by thermoregulatory dysfunction in a subject in need thereof, comprising administering milnacipran and the claims in the co-pending Application is a method for treating same disorder administering milnacipran in combination with 5-HT2a receptor antagonist.

The difference between instant claims and the claims in the copending Application is incorporation of a 5-HT2a-receptor antagonist to treat a same disorder. However, incorporation of additional agent of 5-HT2a receptor antagonist is obvious because Berendensen teaches that the 5-HT2A receptor antagonist are well known in the art for the same treatment. (see, abstract, pages 159-160 section 1). Therefore, the claimed additional compound (5-HT2a receptor antagonist) for the treatment of same disorder in the copending Application is obvious over the instant Application.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7, 13 and 15-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treating vasomotor symptoms", does not reasonably provide enablement for the "preventing vasomotor symptoms". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or preventing vasomotor symptoms in a subject in need thereof, comprising the step of: administering to said subject a therapeutically effective amount of milnacipran or pharmaceutically acceptable salt thereof, wherein said amount is less than about 37.5mg/day. The nature of the invention is extremely complex in that it encompasses the actual prevention of vasomotor symptoms in a subject such that the subject treated with above compounds does not develop vasomotor symptoms.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass **prevention** of vasomotor symptoms in humans, which has potentially many different causes (i.e. many different medical disorders, side-effects of drugs, age related). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually **prevent** vasomotor symptoms is minimal. All of the guidance provided

by the specification is directed towards treatment rather than prevention of vasomotor symptoms.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of vasomotor symptoms.

State of the Art: While the state of the art is relatively high with regard to treatment of vasomotor symptoms (i.e. hot flush), the state of the art with regard to prevention of such disorders is underdeveloped. The state of art, Waldon et al. report that there are significant problems with patient compliance monitoring and communication in prophylactic therapies or in the treatment of slow onset conditions related to vasomotor symptoms and these symptoms are difficult for medical professionals to adequately detect and diagnose. (page 1, [0002], [0003]).

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of vasomotor symptoms in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of **prevention** of vasomotor symptoms.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for prevention of vasomotor

symptoms. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of vasomotor symptoms with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of vasomotor symptoms with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of vasomotor symptoms in a subject by administration of one of the claimed compounds.

Therefore, a method of **preventing** in a subject in need thereof vasomotor symptoms administering a therapeutically effective amount of milnacipran or pharmaceutically acceptable salt thereof, wherein said amount is less than about 37.5mg/day is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 13 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briley (WO 98/36744) in view of Leonard et al. (US 2003/0216366A1).

Briley teaches milnacipran is a useful medicine for the treatment of sleeplessness. (abstract).

Briley does not teach the specific amounts of milnacipran per day set forth in claims 1-7 and the specific subject to be treated set forth in claims 15-21.

Leonard et al. teach treatment of a subject suffering from insomnia. Leonard et al. teach that insomnia (sleeplessness) is one of vasomotor symptoms. (claims 1, 12 and 52). Leonard et al. teach that the subject to be treated is particularly menopausal and post-menopausal woman. ([0002]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ milnacipran for the treatment of vasomotor symptom such as insomnia (sleeplessness) because Briley et al. teach that milnacipran is useful medicament for the treatment of insomnia as taught by Briley and because insomnia is one symptom involved with vasomotor function. One would have been motivated to employ milnacipran for the treatment of vasomotor symptom in order to achieve an expected benefit of relieving sleeplessness which is one of symptoms involved with vasomotor function.

The therapeutically effective amounts per day set forth in claims 1-7 is obvious because Briley teaches that milnacipran is effective medicament for the treatment of insomnia and as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infection would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as

toxicity. For these and other self-evident reasons, it would have been obvious to optimize the therapeutic dosage of milnacipran taught by Briley et al. known to be effective for the treatment of vasomotor symptom. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. With regard to the subject to be treated set forth in claims 15-21 is obvious because Leonard et al. teach that any subject can be treated but preferred subject to be treated are menopausal and post-menopausal woman who is suffering from insomnia. One would have been motivated to employ milnacipran for the treatment of insomnia patients particularly menopausal and post-menopausal woman who is suffering vasomotor symptoms in order to achieve an expected benefit of treating insomnia which is a symptom involving vasomotor taught by Leonard et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Response to Arguments

Applicants' arguments filed January 26, 2007 have been fully considered but they are not persuasive. Applicants argue that the claims 1 –7, 13 and 15- 21 are enable for

the prevention of vasomotor symptoms because Milnacipran is a dual NRI/SRI compound and that the specification in Figure 4 shows an increasing dose of NRI and a 10mg/kg dose of SRI were coadministered, hot flush was abated by 100% at a 3mg/kg dose of an NRI (desipramine) compared with 10mg/kg dose. This is not persuasive because the specification in Fig. 4 provides examples of the alleviation of vasomotor symptoms using a specific NRI compound (desipramine) and a specific SRI compounds (fluoxetine) resulting more efficacious for treating hot flushes with the therapeutic amounts greater than 37.5mg/day. However, it does not show absolute prevention of vasomotor symptom (hot flushes) comprising administration of milnacipran with amounts less than 37.5mg/day. The figure 4 of abated the hot flush by 100% does not guarantee the absolute prevention encompassing future reoccurrence of the symptoms in the subject. Therefore, no data has been presented to establish that Applicants' specific compound milnacipran would completely prevent vasomotor symptoms so that it would not reoccur. Therefore, it is highly speculative. Further, the dosage amounts employed in the tested subject are much higher than what is claimed. Applicants argue that the sleeplessness disclosed by the Briley application is not insomnia or sleep disturbances associated with vasomotor symptoms, as defined in the specification. This is not found persuasive because instant specification [0001] as pointed by the Applicants does not exclude that insomnia is not caused by thermoregulatory dysfunction because it recites the vasomotor symptoms include hot flushes and insomnia among other symptoms caused by thermoregulatory dysfunction. Applicants' attention is drawn to Czeisler et al. (U.S.Patent No. 5,146,927, column 2, lines 443-50),

wherein, it teach that many chronic sleep disturbances (e.g. insomnia) are associated with abnormalities in the core body temperature cycle. Therefore, clearly, the condition of insomnia is associated with vasomotor symptoms caused by thermoregulation. Applicants argue that it would not be obvious to one of the skilled artisan to optimize the level of milnacipran to reach applicants' claimed amount of less than about 37.5mg. This is not persuasive because Briley et al. teach the administration of milnacipran in a subject in need for the treating vasomotor symptoms of insomnia in general and that this method step of preparing milnacipran would comprise a therapeutically effective amount including doses less than 37.5mg. Applicants' therapeutic effective amount would be encompasses by Briley's preparation step of same active agent effective for use in same disorder. Applicants argue that the state of the art actually taught away from lowering the maximum level of milnacipran. This is not persuasive because state of the art actually teaches that milnacipran causes vasomotor symptom at its therapeutic amount. (see enablement rejection, above). Further, Applicants have presented no supporting data that Applicants' claimed compound with claimed amount of less than 37.5mg would actually treat the vasomotor symptoms. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
April 16, 2007